UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

Sandra K. Shoemaker, individually and on behalf of all others similarly situated,

Plaintiffs,

v.

Cardiovascular Systems, Inc., and Laurence L. Betterley,

Defendants.

Civil No. 16-568 (DWF/KMM)

MEMORANDUM OPINION AND ORDER

Bryan L. Bleichner, Esq., Jeffrey D. Bores, Esq., Karl L. Cambronne, Esq., Chestnut Cambronne, PA; and Naumon A. Amjed, Esq., and Ryan T. Degnan, Esq., Kessler Topaz Meltzer & Check LLP, counsel for Plaintiff Sandra K. Shoemaker.

Angus Ni, Esq., Jeremy Robinson, Esq., Bernstein Litowitz Berger & Grossmann LLP; and Gregg M. Fishbein, Esq., Kate M. Baxter-Kauf, Esq., Richard A. Lockridge, Esq., Lockridge Grindal Nauen PLLP, counsel for City of Miami Fire Fighters' & Police Officers' Retirement Trust.

David R. Marshall, Esq., Leah C. Janus, Esq., Fredrikson & Byron, PA; and Michael C. Tu, Esq., Robert M. Stern, Esq., Orrick, Herrington & Sutcliffe LLP, counsel for Defendants.

INTRODUCTION

This matter is before the Court on a Motion to Dismiss Plaintiffs' Amended Class Action Complaint ("Complaint") brought by Defendants Cardiovascular Systems, Inc. ("CSI") and Laurence L. Betterley ("Betterley"). (Doc. No. 52.) For the reasons set forth

below, the Court grants the Motion to Dismiss without prejudice and grants Plaintiffs' request for leave to amend their Complaint.

BACKGROUND

CSI is a publicly traded company that primarily develops and manufactures medical devices for the treatment of peripheral arterial disease and coronary artery disease. (Doc. No. 48 ("Am. Compl.") ¶ 20.) Betterley has been CSI's Chief Financial Officer since April 2008. (*Id.* ¶ 22.) David L. Martin, recently deceased, was CSI's CEO and one of its directors during the relevant time period. (*Id.* ¶ 23.) Plaintiffs are shareholders of CSI who allege that Defendants violated Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 (the "Exchange Act"). Plaintiffs seek to represent a class of shareholders who "purchased or otherwise acquired" CSI's common stock between September 12, 2011 and January 21, 2016. (Am. Compl. at 1.)

I. CSI's Business Model

Around 88% of CSI's business comes from the sale of devices used to treat peripheral arterial disease ("PAD"). (*Id.* ¶ 26.) PAD "typically refers to the chronic obstruction of the arteries supplying the lower extremities due to plaque deposition on the walls of the arteries resulting in inadequate blood flow to the limbs." (Doc. Nos. 55-70 ("Luken Decl.") ¶ 11, Ex. 10 at 2.) The effect of PAD, if left untreated, "may continue to progress to Critical Limb Ischemia ("CLI"), a condition in which the amount of oxygenated blood being delivered to the limb is insufficient to keep the tissue alive." (*Id.*) CLI can lead to a number of adverse health effects up to and including death. (*Id.*) In fact, within a year of a CLI diagnosis, 25% to 30% of patients will die. (*Id.*)

During the relevant period, CSI received FDA approval to sell three different PAD devices for PAD therapy. (Am. Compl. ¶ 34.) The FDA authorized the sale of CSI's Diamondback 360® Peripheral Orbital Atherectomy System in August 2007; CSI's Stealth 360® Orbital Atherectomy System in March 2011; and CSI's Diamondback 360® 60 cm Peripheral Orbital Atherectomy System in February 2014. (Luken Decl. ¶ 11, Ex. 10 at 2.)

CSI has also developed devices to treat coronary artery disease ("CAD"). CAD is the most common type of heart disease in the United States. (*Id.* at 3.) CAD occurs when "plaque builds up on the walls of arteries that supply blood to the heart." (*Id.*) In October 2013, the FDA gave premarket approval for CSI's Diamondback 360® Coronary OAS to treat CAD. (*Id.* at 2.)

II. AKS, FCA, and Off-Label Promotions

CSI operates in a heavily regulated market, which prohibits some conduct that would be legal in less regulated industries. Under the Food, Drug, and Cosmetic Act ("FDCA"), the Food and Drug Administration ("FDA") is vested with, among other things, the responsibility of approving labels for medical devices, which outline the devices' approved uses. James M. Beck & Elizabeth D. Azari, *FDA, Off-Label Use, and Informed Consent: Debunking Myths and Misconceptions*, 53 Food & Drug L.J. 71, 71 (1998). Once approved for particular uses, a physician can still prescribe the device for other, off-label uses. *Id.* at 78. Such off-label uses are a "common and integral feature of medical practice." *Id.* at 79. But even though a physician may prescribe an off-label use, manufacturers may not promote those uses. *Id.* at 102 & n.235. If a manufacturer is

found to have promoted an off-label use, the manufacturer can face a number of penalties, including up to a year in prison and a $1,000 fine. *See* 21 U.S.C. § 333.

Medical devices are also regulated by the federal Anti-Kickback Statute ("AKS").[1] The AKS is a criminal statute that prohibits, among other things, "knowingly and willfully offer[ing] or pay[ing] any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person" to either refer an individual to the person for medical services or to purchase any good that that will be repaid in whole or in part by a federal health care program. 42 U.S.C. § 1320a-7b(b)(2)(B). In short, a violation of the AKS requires: (1) a remuneration to a person or entity in a position to either purchase goods subject to reimbursement by a federal health care program or to refer a patient whose care will be reimbursed by a federal health care program; and (2) that the remuneration could reasonably induce such referral or such purchase. *See Jones-McNamara v. Holzer Health Sys.*, 630 F. App'x 394, 401 (6th Cir. 2015) (citing OIG Supplemental Compliance Program Guidance for Hospitals, 70 Fed. Reg. 4858, 4864 (Jan. 31, 2005)).[2] Courts and the OIG have concluded that a "remuneration" is "virtually anything of value." *Id.* (quoting OIG Compliance Program Guidance for Ambulance Suppliers, 68 Fed. Reg. 14245, 14252 (Mar. 24, 2003)). A person guilty of violating AKS faces up to five years

[1] 42 U.S.C. § 1320a-7b.

[2] The Office of the Inspector General ("OIG") for the Department of Health and Human Services offers guidance on the AKS.

in prison and a fine up to $25,000. 42 U.S.C. § 1320a-7b(b). A violation of the AKS may also be a violation of the federal False Claims Act[3] ("FCA") where a claim submitted to the government includes items or services resulting from a violation of the AKS. *Id.* § 1320a-7b(g).

The AKS has a number of safe harbors, including for providing discounts. *Id.* § 1320a-7b(b)(3)(A). The safe harbor, however, does not offer protection if, among other things, the documentation provided to physicians does not accurately reflect the discount. 42 C.F.R § 1001.952(h)(2); *United States v. Carroll*, 320 F. Supp. 2d 748, 756 (S.D. Ill. 2004) (quoting OIG Clarification of the Initial OIG Safe Harbor Provisions and Establishment of Additional Safe Harbor Provisions Under the Anti-Kickback Statute, 64 Fed. Reg. 63518, 63527 (Nov. 19, 1999)); *see also U.S. ex rel. Banigan v. Organon USA Inc.*, 883 F. Supp. 2d 277, 296 (D. Mass. 2012) (noting that discounts are not covered if they are not passed on to Medicaid).

III. Qui Tam Allegations

On July 15, 2013, a former district sales manager, who worked for CSI from 2012 until February 2013, filed a qui tam[4] action against CSI. (Doc. No. 48-2 ("Qui Tam Complaint") ¶ 9.) The Qui Tam Complaint alleged that CSI had illegally promoted its PAD devices for off-label purposes and had given illegal kickbacks to physicians for

[3] 31 U.S.C. § 3729.

[4] A qui tam action is one filed by a private person on behalf of the government. *Qui Tam*, Black's Law Dictionary (10th ed. 2014).

prescribing the PAD devices. (*See id.* ¶ 10.) The Qui Tam Complaint was expressly incorporated by reference into the Complaint. (Am. Compl. at 1 n.1.)[5]

The Qui Tam Complaint alleges that CSI gave illegal kickbacks to physicians in the form of free trips to training programs at desirable locations in exchange for the physicians buying PAD devices. (Qui Tam Complaint ¶¶ 50-52.) Additionally, CSI allegedly marketed the PAD devices as a revenue generator for physicians as compared to less expensive alternatives. (*Id.* ¶ 59.) CSI also allegedly encouraged physicians to use the PAD devices when they were not medically necessary. (*Id.* ¶ 63.) In addition, the Qui Tam Complaint alleges that CSI gave illegal kickbacks in the form of free products, such as deals where the physicians buy six devices and get one free. (*Id.* ¶ 69.) CSI allegedly offered illegal kickbacks in the form of referrals to doctors in exchange for use of PAD devices. (*Id.* ¶¶ 74, 80-81.) Finally, the Qui Tam Complaint alleges that CSI selected physicians to be paid speakers for CSI's Speaker Bureau based on which physicians used the most PAD devices and who would drive others to use PAD devices. (*Id.* ¶ 88.)

In addition, the Qui Tam Complaint alleges that CSI marketed its PAD devices for off-label uses. Specifically, CSI allegedly informed physicians at training events that its

[5] The Court would caution future plaintiff's counsel from fully incorporating by reference other complaints. Here, while some allegations in the Qui Tam Complaint are repeated by confidential witnesses in the Amended Complaint, other allegations are not and appear only in the Qui Tam Complaint. Counsel, then, is certifying that to the best of his or her "knowledge, information, and belief, formed after an inquiry reasonable under the circumstances . . . the factual contentions have evidentiary support or, if specifically so identified, will likely have evidentiary support after a reasonable opportunity for further investigation or discovery." 15 U.S.C. § 78u-4(c); Fed. R. Civ. P. 11(b)(3).

PAD Devices, which were allegedly approved to be used on certain blood vessels in certain parts of the body, could also be used for other vessels in other body parts. (*Id.* ¶¶ 97, 101, 106.)

IV. Qui Tam Settlement and Aftermath

At first, the Qui Tam Complaint was filed under seal, concealing its existence from CSI. (*See* Am. Compl. ¶ 8; Memo. at 7.)[6] On May 9, 2014, CSI announced that the U.S. Attorney's Office for the Western District of North Carolina had sent CSI notice that it was investigating the Qui Tam Complaint. (Am. Compl. ¶ 10.) On July 8, 2015, the Qui Tam Complaint was unsealed. (Memo at 7; Luken Decl. ¶ 26, Ex. 25.) On June 29, 2016, CSI settled the Qui Tam Complaint in exchange for $8 million and agreeing to a Corporate Integrity Agreement. (Opp. at 9.) CSI did not admit any wrongdoing as part of the settlement. (Doc. No. 74 ("Robinson Decl.") ¶ 12, Ex. 5 ("Settlement Agreement") at 2.)

In the aftermath of the announcement of the Qui Tam Complaint, CSI's stock price fell. (Am. Compl. ¶ 124.) Shareholders filed suit in the Central District of California and in the District of Minnesota. (Memo. at 8.) On March 26, 2016, this Court appointed Plaintiffs as Co-Lead Plaintiffs. (Doc. No. 25.) And on June 28, 2016, Plaintiffs filed this Complaint. (Doc. No. 48.)

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[6] Defendants' Memorandum in Support of their Motion to Dismiss (Doc. No. 54) is cited as "Memo." Plaintiffs' Memorandum in Opposition to Defendants' Motion to Dismiss (Doc. No. 73) is cited as "Opp." Defendants' Reply brief (Doc. No. 76) is cited as "Reply."

V. Plaintiffs' Complaint

Plaintiffs claim that in early 2012, Kevin Kenny (Executive Vice President of Sales and Marketing) and Jim Breidenstein (Vice President of Sales) implemented a scheme whereby CSI began violating the AKS and the FCA by: (1) providing kickbacks to physicians for using PAD devices, which took the form of either referrals, discounted products, or assistance in establishing office-based laboratories; (2) encouraging physicians to use PAD devices when they were not medically necessary; (3) hiding products so they would be reordered or channel stuffing;[7] and (4) promoting the product for off-label uses. The scheme was allegedly in place from when Breidenstein joined CSI in 2012 until May 9, 2014, when CSI received notice of the Qui Tam Complaint. (*See* Am. Compl. ¶¶ 34, 60.)

In addition to allegations from the Qui Tam Complaint, Plaintiffs also used an investigator who successfully contacted fourteen former CSI employees. The former employees did not sign declarations regarding CSI's sales practices. Instead, Plaintiffs have attributed the information in the form of confidential witness statements. In response to the statements, CSI claims that it spoke with eight of the fourteen witnesses. And according to CSI, each of the eight refuted their attributed statements, and two signed declarations. (Memo. at 20.) The confidential witnesses ("CWs") make the following allegations:

[7] Channel stuffing is a practice of over shipping goods to inflate sales.

CW1 was a District Sales Manager in New York from 2010 to 2012. According to CW1:

- CSI provided free products through "'buy some get some free' deals," but recorded them as lost inventory. (Am. Compl. ¶ 57.)
- CSI targeted third-party physicians to refer patients to physicians who used PAD devices. (*Id.* ¶ 69.)
- Physicians used PAD devices when they were not medically necessary. (*Id.* ¶ 88.)
- CSI provided physicians with documents that promoted CSI's PAD devices as revenue generators. (*Id.* ¶ 90.)

CW2 was a Sales Specialist in Florida from 2012 to 2014. According to CW2:

- CSI trained sales representatives and physicians to use PAD devices with smaller, unapproved catheters. (*Id.* ¶ 43.)
- CSI provided physicians with documents that promoted CSI's PAD devices as revenue generators. (*Id.* ¶¶ 43, 91.)
- CSI gave away free products in buy-some, get-some-free deals. (¶¶ 58-59.) The deals were regularly touted by Breidenstein. (*Id.*)
- CSI marketed its referral network, including by inviting physicians to dinner. (*Id.* ¶ 70.)
- CSI offered free products to office-based laboratories and otherwise supported their operations. (*Id.* ¶ 82.)
- Physicians performed medically unnecessary procedures to use more CSI PAD devices, which was encouraged by "CSI officials." (*Id.* ¶¶ 88-90.)

CW3 was an executive and Vice President from 2006 until 2012, and he heard about the existence of illegal sales practices, which were implemented by Breidenstein and Kenny. (*Id.* ¶ 60.)

CW4 was a referral marketer from 2008 until 2010. In 2010, he became a District Sales Manager until 2012. He worked in the Southeastern United States. According to CW4:

- CSI "incentivized sales representatives to offer buy one, get one free deals at the end of the quarter." (*Id.* ¶ 61.)
- Before becoming a salesperson, CW4 would arrange meetings and lunches between physicians who would potentially refer patients to the physicians using PAD devices. (*Id.* ¶ 71.)
- CSI employees hid customers' PAD devices in hospitals to cause reorders. (*Id.* at 87.)

CW5 was a Field Clinical Specialist from 2014 until 2015. Plaintiffs do not allege where CW5 worked. According to CW5, sales representatives encouraged physicians to use PAD devices even when unnecessary. (*Id.* ¶ 44.)

CW6 was a Regional Manager from 2009 to 2012. Plaintiffs did not disclose in which region CW6 worked. CW6 allegedly stated:

- CSI encouraged office-based laboratories to unnecessarily use PAD devices and offered them free devices and large discounts. (*Id.* ¶ 83.)
- Breidenstein and Kenny were the ones giving the "unethical marching orders." (*Id.* ¶ 103.)
- CW6 was allegedly terminated for not engaging in the illegal practice. (*Id.* ¶ 103.)

CW7 was a District Sales Manager in Ohio from 2010 to 2012. According to CW7, CSI routinely offered "buy so many, get so many free deals to customers." (*Id.* ¶ 62.)

CW8 was a Regional Sales Manager in Florida from 2015 to 2016. According to CW8, after Breidenstein's departure, CSI was a "different place." (*Id.* ¶ 118.)

CW9 was a shipping and receiving clerk in Minnesota from 2011 to 2013. CW9 was responsible for shipping and receiving PAD devices. Apparently, CW9 saw an increase in PAD shipments near the end of the quarter and determined that these shipments were returned. (*Id.* ¶¶ 94-95.) CW9 allegedly implemented a test where he would mark certain packages to track that the same packages were being returned. (*Id.* ¶ 94.)

CW10 was a District Sales Manager in Florida from 2014 to 2015. According to CW10:

- Buy-some, get-some-free deals were quid pro quo, and the offers were individualized to each customer. (*Id.* ¶ 63.)
- Physicians used PAD devices when they were not medically necessary. (*Id.* ¶ 88.)
- CSI provided physicians with documents that promoted CSI's PAD devices as revenue generators. (*Id.* ¶ 91.)

CW11 was a District Sales Manager in Massachusetts from 2010 to 2013. According to CW11:

- Breidenstein implemented "shady" sales practices to drive sales, including buy-some, get-some-free deals. (*Id.* ¶ 64.)
- CSI encouraged physicians to open office-based laboratories. (*Id.* ¶ 83.)
- CW11 heard of CSI encouraging physicians to use multiple PAD devices. (*Id.* ¶ 92.)

CW12 was a District Sales Manager in Alabama from 2012 to 2014. According to CW12:

- CSI encouraged buy-some, get-some-free deals, including with office-based laboratories. (*Id.* ¶ 65.)
- CSI marketed PAD devices as revenue generators for physicians. (*Id.* ¶¶ 90-91.)
- Physicians used PAD devices when they were not medically necessary. (*Id.* ¶ 88.)

CW13 was a District Sales Manager in Colorado and Wyoming from 2011 to 2014. According to CW13:

- Educational programs were really referral opportunities for CSI to let referring physicians know of local physicians who used CSI devices. (*Id.* ¶ 72.)
- Physicians used PAD devices when they were not medically necessary. (*Id.* ¶ 89.)

CW14 was a District Sales Manager in New York from 2012 to 2013. According to CW14:

- CSI would help physicians set up office-based laboratories, including helping the newly formed labs receive preferred pricing from other suppliers. (*Id.* ¶ 84.)
- Physicians used PAD devices when they were not medically necessary. (*Id.* ¶ 92.)
- Breidenstein implemented a sales approach of selling products as aggressively as possible. (*Id.* ¶ 103.)

VI. Alleged Misstatements

Plaintiffs allege that CSI made various misstatements and omissions each premised on the same factual predicate: CSI engaged in widespread illegal activity. Broadly, Plaintiffs allege six categories of misstatements:

> (1) Statements about past sales growth that Defendants falsely attributed to legitimate practices;
>
> (2) Statements about future sales growth that were falsely attributed to legitimate practices;
>
> (3) Statements about CSI's revenues made while omitting the truth about the Company's illegal sales practices;
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> (4) Statements about CSI's legal and regulatory compliance;
>
> (5) False signed Sarbanes-Oxley Act ("SOX") certifications guaranteeing the accuracy of the Company's financial statements; and
>
> (6) Statements and omissions about losses that CSI suffered after discontinuing its illegal sales tactics, as well as costs incurred from sales-force reorganizations necessitated by the end of illegal sales activities. These include both affirmative falsehoods as to the causes of those losses as well as omissions as to their true causes.

(Opp. at 11 (internal citations omitted).) Defendants moved to dismiss on a number of grounds, including that Plaintiffs have failed to adequately plead facts demonstrating illegal conduct.

DISCUSSION

I. Legal Standard

In deciding a motion to dismiss pursuant to Rule 12(b)(6), a court assumes all facts in the complaint to be true and construes all reasonable inferences from those facts in the light most favorable to the complainant. *Morton v. Becker*, 793 F.2d 185, 187 (8th

Cir. 1986). In doing so, however, a court need not accept as true wholly conclusory allegations, *Hanten v. Sch. Dist. of Riverview Gardens*, 183 F.3d 799, 805 (8th Cir. 1999), or legal conclusions drawn by the pleader from the facts alleged, *Westcott v. City of Omaha*, 901 F.2d 1486, 1488 (8th Cir. 1990). A court may consider the complaint, matters of public record, orders, materials embraced by the complaint, and exhibits attached to the complaint in deciding a motion to dismiss under Rule 12(b)(6). *Porous Media Corp. v. Pall Corp.*, 186 F.3d 1077, 1079 (8th Cir. 1999).

To survive a motion to dismiss, a complaint must contain "enough facts to state a claim to relief that is plausible on its face." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). Although a complaint need not contain "detailed factual allegations," it must contain facts with enough specificity "to raise a right to relief above the speculative level." *Id*. at 555. As the United States Supreme Court reiterated, "[t]hreadbare recitals of the elements of a cause of action, supported by mere conclusory statements," will not pass muster under *Twombly*. *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (citing *Twombly*, 550 U.S. at 555). In sum, this standard "calls for enough fact[s] to raise a reasonable expectation that discovery will reveal evidence of [the claim]." *Twombly*, 550 U.S. at 556.

In addition to these general pleading standards, the PSLRA imposes a heightened pleading standard in cases alleging securities fraud. *Lustgraaf v. Behrens*, 619 F.3d 867, 873 (8th Cir. 2010). Under the PSLRA, complaints in a securities fraud action must "specify each statement alleged to have been misleading, the reason or reasons why the statement is misleading," and must "state with particularity facts giving rise to a strong

inference that the defendant acted with the required state of mind" (the "scienter requirement"). 15 U.S.C. § 78u-4(b)(1)-(2); *see also Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 321 (2007). One purpose of the PSLRA was to "put an end to the practice of pleading fraud by hindsight." *Elam v. Neidorff*, 544 F.3d 921, 927 (8th Cir. 2008). But the heightened pleading standard does not amount to an obligation on securities fraud plaintiffs to ultimately prove their allegations, as that "is an altogether different question" from adequately pleading securities fraud. *Matrixx Initiatives, Inc. v. Siracusano*, 131 S. Ct. 1309, 1325 (2011).

Plaintiffs allege that Defendants violated the anti-fraud provisions of Section 10(b) of the Exchange Act and SEC Rule 10b-5. Section 10(b) of the SEC Act makes it "unlawful for any person, directly or indirectly . . . [t]o use or employ, in connection with the purchase or sale of any security . . . any manipulative or deceptive device or contrivance in contravention of" SEC rules. 15 U.S.C. § 78j(b). SEC Rule 10b-5 states that it is:

> unlawful for any person, directly or indirectly, by the use of any means or instrumentality of interstate commerce . . . [t]o employ any device, scheme, or artifice to defraud, [t]o make any untrue statement of a material fact or to omit to state a material fact necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading, or [t]o engage in any act, practice, or course of business which operates or would operate as a fraud or deceit upon any person, in connection with the purchase or sale of any security.

17 C.F.R. § 240.10b-5(a)-(c). A plaintiff asserting liability under Section 10(b) and/or Rule 10b–5 must adequately allege: "'(1) a material misrepresentation or omission by the defendant; (2) scienter; (3) a connection between the misrepresentation or omission

and the purchase or sale of a security; (4) reliance upon the misrepresentation or omission; (5) economic loss; and (6) loss causation.'" *Minneapolis Firefighters' Relief Ass'n v. MEMC Elec. Materials, Inc.*, 641 F.3d 1023, 1028 (8th Cir. 2011) (quoting *Stoneridge Inv. Partners, LLC v. Sci.-Atl., Inc.*, 552 U.S. 148, 157 (2008)).

II. Judicial Notice

The parties have submitted a number of documents related to the motion to dismiss. On a motion to dismiss, courts are not strictly limited to the allegations of the complaints and documents attached to it. *Dittmer Props., L.P. v. F.D.I.C.*, 708 F.3d 1011, 1021 (8th Cir. 2013). Instead, courts can consider "matters incorporated by reference or integral to the claim, items subject to judicial notice, matters of public record, orders, items appearing in the record of the case, and exhibits attached to the complaint whose authenticity is unquestioned without converting the motion into one for summary judgment." *Id.* (quoting *Miller v. Redwood Toxicology Lab., Inc.*, 688 F.3d 928, 931 n.3 (8th Cir. 2012) (internal quotation marks omitted)).

Defendants have requested judicial notice or otherwise submitted: (1) SEC filings, including CSI's 10-Ks, 8-Ks, press releases, and earnings calls that occurred around the Class Period; (2) instructions for CSI's Stealth 360® Orbital Atherectomy System, which was approved in March 2011 and treats PAD; (3) some of CSI's internal policies; (4) former CEO Martin's 10b5-1 trading plans and modifications; and (5) declarations disputing some of Plaintiffs' confidential witnesses. (*See* Luken Decl.) Plaintiffs submitted declarations from members of Plaintiffs' litigation team discussing their use of confidential witnesses in drafting their complaint. Plaintiffs also request the court

consider: (1) CSI's settlement agreement for the Qui Tam Complaint; (2) the corporate integrity agreement, which was part of the settlement and outlines procedures for CSI to monitor for AKS & the FCA violations; and (3) instructions for CSI's Diamondback 360® Coronary Orbital Atherectomy System, which was approved in October 2013 and treats CAD. (*See* Robinson Decl.) Plaintiffs allege that all of these documents are publicly available from the SEC (for the settlement agreement) or from the FDA (for the instructions). (Doc. No. 75.) Defendants do not oppose Plaintiff's motion for judicial notice. And Plaintiffs oppose Defendants' submissions only to the extent that Defendants try to resolve factual disputes. (Opp. 12-14.)

Here, the Court takes judicial notice of the public statements and SEC filings, including the settlement agreement and corporate integrity agreement. *See Fla. State Bd. of Admin. v. Green Tree Fin. Corp.*, 270 F.3d 645, 663 (8th Cir. 2001). The Court also takes judicial notice of the documents outlining CSI's internal policies, which are contemplated by the Complaint and neither party disputes their authenticity. *Dittmer Props.*, 708 F.3d at 1021. Additionally, the Court takes judicial notice of the device instructions. *Garross v. Medtronic, Inc.*, 77 F. Supp. 3d 809, 818 (E.D. Wis. 2015). The Court also takes judicial notice of Martin's 10b5-1 trading plan and modifications. *Glaser v. The9, Ltd.*, 772 F. Supp. 2d 573, 593 n.14 (S.D.N.Y. 2011). The Court, however, will not consider the parties' declarations, which address the veracity of the confidential witnesses or their accounts. Courts cannot resolve fact disputes on a motion to dismiss. Similarly, Rule 201 allows a court to take judicial notice of only those facts that are not in dispute. *Kushner v. Beverly Enters., Inc.*, 317 F.3d 820, 832 (8th Cir.

2003) (citing Fed. R. Evid. 201). Thus, because the statements of the confidential witnesses are in dispute, the Court cannot consider the declarations at this stage.

III. False And Misleading Statements

Plaintiffs' case is premised on the notion that Defendants engaged in widespread illegal sales practices. And as a result of these illegal activities, Plaintiffs contend, a number of Defendants' public statements were false and misleading. The PSLRA imposes a heightened pleading requirement for securities fraud cases. *Pub. Pension Fund Grp. v. KV Pharm. Co.*, 679 F.3d 972, 980 (8th Cir. 2012). As part of that heightened pleading requirement, a plaintiff must "specify each statement alleged to have been misleading [and] the reason or reasons why the statement is misleading[.]" *Id.* (alterations in the original) (quoting 15 U.S.C. § 78u–4(b)(1)). To satisfy this heightened pleading standard, "the circumstances of the fraud must be stated with particularity, including such matters as the time, place and contents of false representations, . . . [t]his means the who, what, when, where, and how." *Id.* (alteration in the original) (internal quotation marks omitted).

At the outset, the parties disagree whether Plaintiffs have adequately pleaded that CSI engaged in illegal conduct. In fact, Plaintiffs argue that their Complaint can survive a motion to dismiss even without alleging facts that, if true, would violate either the AKS or the FCA. (Opp. at 13.) The better view, however, is that Plaintiffs must plead particular facts that, if true, would constitute illegal conduct. *See In re Key Energy Servs., Inc. Sec. Litig.*, 166 F. Supp. 3d 822, 863, 872 (S.D. Tex. 2016) (concluding that the plaintiffs' claim failed in part because they failed "to plead any facts showing that

there were FCPA violations"); *see also Minneapolis Firefighters' Relief Ass'n v. Medtronic, Inc.*, No. Civ. 08-6324, 2010 WL 11469576, at *4 (D. Minn. Feb. 3, 2010) ("Plaintiffs have come forward with evidence that, if believed, establishes that Medtronic purposefully promoted the off-label use of Infuse. Defendants' Motion cannot be granted on this basis."). *But see Sapssov v. Health Mgmt. Assocs., Inc.*, 22 F. Supp. 3d 1210, 1226 (M.D. Fla. 2014) ("The Court finds that plaintiffs in this case need not allege a violation of the FCA in order to properly plead their securities fraud cause of action."), *aff'd*, 608 F. App'x 855 (11th Cir. 2015). Congress passed the PSLRA to protect against meritless strike suits. *Tellabs*, 551 U.S. at 313. Allowing shareholders to sue based on conclusory allegations that a company has engaged in widespread illegal conduct without adequately pleading facts that demonstrate illegal conduct would just allow strike suits by another name. Thus, for Plaintiffs' Section 10(b) and Rule 10b-5 claims to survive a motion to dismiss, Plaintiffs must allege facts that, if true, would constitute illegal conduct.

Plaintiffs rely on confidential witnesses and the Qui Tam Complaint to support their general assertion that CSI violated the AKS and FCA by: (1) promoting off-label uses of CSI's PAD devices; (2) offering discounts to physicians for purchasing PAD devices; and (3) working to cause referrals of patients to physicians who prescribed PAD devices.

A. Confidential Witnesses

Plaintiffs support the allegations in their complaint with statements from confidential witnesses. Unlike other factual allegations in a complaint, courts are not

required to wholly accept as true statements from a confidential witness. Recognizing that confidential witnesses could have a variety of reasons for speaking to plaintiff's counsel, courts routinely evaluate and disregard the statements on a motion to dismiss. *Minneapolis Firefighters' Relief Ass'n v. MEMC Elec. Materials, Inc.*, 641 F.3d 1023, 1030 (8th Cir. 2011) (citing *Higginbotham v. Baxter Int'l, Inc.*, 495 F.3d 753, 757-58 (7th Cir. 2007)). Courts may consider a number of factors when deciding what weight to give statements from confidential witnesses. *In re Nash Finch Co.*, 502 F. Supp. 2d 861, 874 (D. Minn. 2007). A complaint can be supported with statements from a confidential witness when the witness is "described in the complaint with sufficient particularity to support the probability that a person in the position occupied by the source would possess the information alleged." *Id.* (quoting *Cal. Pub. Employees' Ret. Sys. v. Chubb Corp.*, 394 F.3d 126, 146 (3d Cir. 2004)). Things courts consider include "the level of the detail provided by the confidential witnesses, the corroborative nature of the other facts alleged (including from other sources), the coherence and plausibility of the allegations, the number of sources, the reliability of the sources, and similar indicia." *Id.* In *Nash Finch*, the court concluded that it was probable that the confidential witnesses possessed the alleged information "based on job title, job description, and time period." *Id.*

Additionally, a complaint must allege in detail how the confidential witness came to possess the information. *In re Commtouch Software Ltd. Sec. Litig.*, Civ. No. 01-719, 2002 WL 31417998, at *10 (N.D. Cal. July 24, 2002). The complaint must contain enough detail to determine whether the confidential witness has personal knowledge or whether the witness is "merely regurgitating gossip and innuendo." *See id.* at *3.

Here, Plaintiffs, for the most part, have failed to adequately plead the confidential witnesses' roles[8] or how they came into possession of the information. In particular, Plaintiffs have failed to allege the job duties for the confidential witnesses.[9] As a result, the Court disregards the statements of those confidential witnesses for whom Plaintiffs did not provide a description of the witnesses' job duties.

Additionally, Plaintiffs' confidential witnesses, at times, merely relay office gossip. For example, CW3 "heard" about allegedly illegal sales practices. (Am. Compl. ¶ 60.) Similarly, vague allegations from witnesses that CSI had implemented "shady"

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[8] Plaintiffs did allege facts regarding CW9's job duties. (Am. Compl. ¶¶ 94.) According to Plaintiffs, CW9 was a shipping-and-receiving clerk who was responsible for shipping PAD devices. (*Id.*) CW9 apparently noticed that shipments increased at the end of the quarter and many would be returned. (*Id.*) Plaintiffs' suggestion, then, is that CSI engaged in channel stuffing, a practice of over shipping goods to inflate sales. (*See id.*) As alleged, however, Plaintiffs have failed to explain how a shipping-and-receiving clerk could discern legitimate orders from illegitimate ones. Moreover, many of Plaintiffs' other confidential witnesses state that CSI would engage in a fire-sale at the end of each quarter, which would seemingly result in additional shipments. (*See, e.g.*, *id.* ¶¶ 58, 61, 65.) Plaintiffs have failed to reconcile the inconsistencies coming from CSI employees who would purportedly be closer to the sales process. Thus, the Court concludes that it is less probable that CW9 would possess information regarding CSI's sales practice. The Court therefore gives CW9's statements less weight.

[9] The circumstances of this case highlight the deficiency: Plaintiffs have provided the Court with no basis to evaluate the confidential witnesses. Does a district manager in New York have the same responsibilities as one in Wyoming? On what basis does a district sales manager or sales specialist conclude that doctors were providing medically unnecessary procedures? How does a sales specialist know kickbacks to healthcare providers "absolutely occurred" and that Medicare fraud was "rampant?" *See In re Commtouch*, 2002 WL 31417998, at *10; *see also Ill. Farmers Ins. Co. v. Mobile Diagnostic Imaging, Inc.*, No. 13-2820, 2014 WL 4104789, at *12 (D. Minn. Aug. 19, 2014) ("Of course, the conclusory statement that the scans were medically unnecessary is not entitled to the assumption of truth.").

practices or that CSI was a "different place" after Breidenstein left are not detailed enough to be reliable. (*Id.* ¶¶ 64, 118.) Thus, the Court also disregards the confidential witnesses' statements to the extent they are vague or based on second-hand knowledge. Plaintiffs are therefore left with more generalized allegations from the Qui Tam Complaint of CSI's off-label promotions, discounts, and referrals.

B. Off-Label Promotions

Plaintiffs allege that CSI's PAD devices are FDA-approved for use with 6-French catheters and to be used only below the waist. (*Id.* ¶¶ 40, 46.) The French Catheter Scale is the common measurement scale used for catheters: the smaller the number, the smaller the catheter size. (*Id.* ¶ 39.) Plaintiffs allege different instances of CSI purportedly marketing PAD devices for smaller catheters or for use above the waist. Although the Court is obligated to accept as true Plaintiffs' factual allegations, the Court does not need to accept Plaintiffs' conclusory allegations or legal conclusions. *Hanten*, 183 F.3d at 805; *Westcott*, 901 F.2d at 1488. Moreover, under the PSLRA, Plaintiffs must plead certain facts with particularity, including "how" a statement is false. *KV Pharm. Co.*, 679 F.3d at 980.

Here, Plaintiffs fail to plead with particularity the FDA's restriction on CSI's PAD devices. Plaintiffs nakedly allege the FDA limitations, but they fail to buttress this allegation with any support. Plaintiffs do not quote the purported limiting instructions. Nor do Plaintiffs provide the instructions either as an attachment or in support of their

opposition brief.[10] Thus, Plaintiffs have failed to plead with particularity that CSI promoted off-label use of its PAD devices.

Plaintiffs also allege that CSI promoted their PAD devices to be used to treat blockages in coronary arteries. (Am. Compl. ¶ 46.) Plaintiffs point to allegations in the Qui Tam Complaint that state CSI provided reimbursement coding to doctors for coronary uses, but the coding document explicitly states that CSI does not sell any devices for those codes. (*Id.* ¶ 48.) Other than the Qui Tam Complaint, Plaintiffs do not cite any confidential witnesses, doctors, patients, or insurers to support this allegation.[11] Thus, Plaintiffs have failed to plead with particularity that CSI promoted off-label uses of its PAD devices.

C. Discounts

Plaintiffs also allege that CSI gave illegal discounts to physicians in the form of agreements where the doctors bought some devices and received others free. Under the AKS, however, manufacturers are allowed to provide discounts so long as the discount is

[10] Plaintiffs provided the instructions for CSI's CAD device, which provides that the minimum catheter size used should be a 6-French, but no such restriction exists in the PAD device instructions provided by Defendants. (*Compare* (Robinson Decl. ¶ 12, Ex. 7 at 3), *with* (Luken Decl. ¶ 2, Ex. 1 at 34).)

[11] In fact, only CW2 and CW5 allegedly made any statements about off-label uses. CW2, a Sales Specialist, apparently observed training and promotional materials for PAD devices to be used in narrower blood vessels. Plaintiffs, however, have failed to demonstrate that such use is off-label. CW5, a Field Clinical Specialist, made generic allegations that sales representatives encouraged physicians to use PAD devices in every instance, even when not indicated. (Am. Compl. ¶ 44.) But such generalized statements are not particular enough to be given much weight. *See Nash Finch*, 502 F. Supp. 2d at 874.

documented and passed on to the government. *See* 42 C.F.R § 1001.952(h). In their Complaint, Plaintiffs do not allege with particularity that the discounts were not documented or that the discounts were not passed on to the government. Thus, Plaintiffs have failed to plead with particularity that Defendants violated the AKS by providing discounts to physicians.

D. Referrals and Other Kickbacks

Plaintiffs also allege that CSI implement various schemes to cause physicians to use CSI's PAD devices, including helping establish office-based laboratories, trainings, introducing doctors for referrals, and having lunches and dinners with doctors. The elements of a violation of the AKS requires: (1) a remuneration to a person or entity in a position to either purchase goods subject to reimbursement by a federal health care program or to refer a patient whose care will be reimbursed by a federal health care program; and (2) that the remuneration could reasonably induce such referral or such purchase. *See Jones-McNamara v. Holzer Health Sys.*, 630 F. App'x 394, 401 (6th Cir. 2015) (citing OIG Supplemental Compliance Program Guidance for Hospitals, 70 Fed. Reg. 4858, 4864 (Jan. 31, 2005)). The OIG has interpreted "remuneration" as being "virtually anything of value." *Id.* Plaintiffs, however, have failed to allege with particularity that the remuneration was directed toward a person capable of referring patients or purchasing PAD devices. Moreover, Plaintiffs have failed to allege that the remuneration could induce a person to refer a patient or purchase PAD devices. Plaintiffs rely heavily on CSI introducing physicians to other physicians who would prescribe PAD devices, but Plaintiffs fail to allege what remuneration was offered to the referring

physician or how such introductions violate the AKS. (*See* Am. Compl. ¶¶ 67-77.) Thus, Plaintiffs have failed to adequately plead that CSI violated the AKS.

Plaintiffs' claim for securities fraud is premised on allegedly illegal conduct that was not disclosed, which therefore rendered various public statements misleading. Because Plaintiffs' claim is predicated on illegal conduct, Plaintiffs must plead facts that, if true, would constitute illegal conduct. Here, Plaintiffs have failed to adequately plead that CSI was engaged in illegal conduct. The Court therefore dismisses Plaintiffs' Complaint without prejudice and grants their request for leave to amend the Complaint.

IV. Section 20(a) of the Exchange Act

Plaintiffs argue that Betterley is liable under Section 20(a) of the Exchange Act, which establishes joint and several liability for "[e]very person who, directly or indirectly, controls any person liable" for violations of the securities laws, "unless the controlling person acted in good faith and did not directly or indirectly induce the act or acts constituting the violation or cause of action." 15 U.S.C. § 78t.

A claim under Section 20(a) for control person liability is derivative of a primary claim, and therefore the failure to satisfactorily plead a Section 10(b)/Rule 10b-5 claim also precludes a Section 20(a) claim. *See, e.g.*, *Lustgraaf*, 619 F.3d at 874. Because the Court dismisses without prejudice Plaintiffs' primary claim, the Court likewise dismisses Plaintiffs' Section 20(a) claim with leave to amend.[12]

[12] The PSLRA requires that "upon final adjudication of the action, the court shall include in the record specific findings regarding compliance by each party and each attorney representing any party with each requirement of Rule 11(b) of the Federal Rules

(Footnote Continued on Next Page)

ORDER

Based upon the foregoing, **IT IS HEREBY ORDERED:**

1. Defendants' Motion to Dismiss Plaintiffs' Class Action Complaint (Doc. No. [52]) is **GRANTED** consistent with the memorandum above.

2. Plaintiffs' Amended Complaint (Doc. No. [48]) is **DISMISSED WITHOUT PREJUDICE**.

3. Plaintiffs' request for leave to amend is **GRANTED**.

4. Plaintiffs shall file an amended complaint within 90 days of the date of this order.

Dated: March 29, 2017

s/Donovan W. Frank
DONOVAN W. FRANK
United States District Judge

(Footnote Continued From Previous Page)
of Civil Procedure as to any complaint, responsive pleading, or dispositive motion." 15 U.S.C. § 78u-4(c)(1). While the PSLRA does not define "final adjudication," a court's dismissal without prejudice with leave to amend is not a "final adjudication." *See Hilkene v. WD-40 Co.*, Civ. No. 04-2253, 2007 WL 470830, at *1 (D. Kan. Feb. 8, 2007) (collecting cases); *see also In re Charter Commc'ns*, 519 F.3d 730, 731 (8th Cir. 2008) (noting that final adjudication occurred at the entry of a Rule 54(b) final judgment). Thus, the Court concludes that it is not mandated to make such a finding at this time.